

REMARKS

Claims 1-15, 51, 52, and 56-58 are pending in the application. Claims 7, 9, 15, 51, and 54-57 have been amended. Claims 16-50, 53 and 54-55 are cancelled.

Offer to Surrender

The Office Action requires an offer to surrender the original patent grant or an actual surrender (37 C.F.R. §1.178) and advises that this reissue housekeeping duty may be deferred until the time subject matter is actually indicated to be allowable. As claims 1-6 are indicated to be allowable, the time for such offer appears to be now; however, the offer to surrender has already been made and forms part of the original reissue submission. Therefore, the requirement seems to have been met.

Drawings

Please find enclosed a clean copy of each drawing sheet from the printed patent at the time the reissue application was filed.

Election/Restriction Requirements

The Patent Owner objects to the Examiner's division of the claims into six distinct inventions. The Patent Owner also objects to the Examiner's statement that because the Patent Owner "has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits" (Office Action at 12). The Patent Owner respectfully disputes and traverses this position because the doctrine of constructive election is unknown to the Patent Owner. As to the Group I through Group VI claims, these are related as the disclosed plants, plant characteristics, and the seed from which the plants can be grown, i.e., they are capable of use together and coexist in the Enola variety. It does not matter that the searches may be different, as there is no legal significance to restriction in the PTO search classification system. However, the Patent Owner elects with traverse the invention defined by the Examiner's constructive restriction determination. The Patent Owner provisionally cancels claims 16-50 and 53 without prejudice, subject to reinstatement by the Examiner after consideration of these remarks.

Claim Objections

The Patent Owner has made the changes to claims 15 and 58 directed by the

Examiner. Claim 55 has been cancelled.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

The Examiner has rejected claims 8-15, 51, 52 and 54-58 are invalid under 35 U.S.C. § 112, 1st paragraph, on the ground that they fail to meet the description requirement. As stated below, claims 54 and 55 have been cancelled, and the claims in issue are 8-15, 51, 52 and 56-58.

Examiner's position is that there is a *prima facie* case of invalidity under 35 U.S.C. § 112, 1st paragraph, because it is not clear from the specification if applicant "was in possession of other *Phaseolus vulgaris* cultivars that meet the claimed genus of *Phaseolus vulgaris* plants producing seed with the characteristic of yellow seed coat of from about 7.5 Y 8.5/4 to about 7.5 Y 8.5/6 in the Munsell Book of Color when viewed in natural light. Because Patent Owner has not described a representative number of cultivars of the claimed genus, Patent Owner has not adequately described the claimed genus" (Office Action p.16).

The essential predicate of this position is that the Patent Owner "describes" a single cultivar, Enola (seed deposited as ATCC Accession Number 209549). However, the seeds deposited with the ATCC are not the seeds of a single genetic entity. Rather, the seeds represent a variety of genetic entities, with a range of sizes, shapes and colors, both seed coat and hilar ring. Furthermore, when a growout was conducted using seeds from the same source as the ATCC seeds, the plants, pods and seeds displayed a comparable diversity of characteristics. See the attached Declaration of Polly Proctor, paragraphs 12-14. This genetic diversity of the ATCC seeds is confirmed by genetic testing using AFLP (amplified fragment length polymorphism). See the attached Declaration of Laura L. Conley, paragraphs 2, 15 and 16.

This genetic diversity is not surprising. The cultivar of the invention was developed from a highly diverse collection of seeds. They were selected from a bag of pintos, blacks and speckles, as well as some tan and yellow-tan beans, which were those selected by the inventor for planting and further selection. These beans differed from one another in size, shape, seed coat color and hilar ring color. To the best of the inventor's recollection, the seed coat colors would have fallen on the 2.5Y page of the *Munsell Book of Color*.

The ATCC deposit is part of the disclosure of the patent in issue. One of skill in the art would readily recognize that the cultivar of the invention came from a variety of yellow beans. The Examiner's assertion that the Patent Owner "does not describe other cultivars with the claimed characteristics" is incorrect (Office Action p. 14). The Examiner has not carried the burden of making out a *prima facie* case of invalidity under 35 U.S.C. § 112, 1st paragraph.

Two other points merit brief comment. The Examiner's legal position is based on *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed Cir. 1997). It is difficult to see how this law can justify rejection of claims 8-15 when those claims were allowed by Examiners Robinson and Kimball roughly twenty-one months after *University of California* was decided. The Patent Owner respectfully submits that the Examiner is incorrectly changing the law relevant to this application by unduly broadening the narrow holding of *University of California*.

At issue in *University of California*, was whether a patent specification that adequately described a gene for rat insulin cDNA and taught prophetic examples of how to isolate cDNA from other mammals was sufficient to support claims addressing cDNA from the other mammals. *University of California* does not stand for a hard rule that a claimed plant 'genus' claim must be supported by a sufficient number of disclosed species falling within the genus. *University of California* merely stands for the proposition that cDNA from one species having a particular function does not necessarily teach cDNA having the same function in all other species in a manner that can be recognized by others when the structure of the cDNA from other species is not specifically disclosed:

In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by

function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. *Id.* at 1406.

In the present proceeding, we are not concerned with claims addressing chemical structure or cDNA. The art of plant breeding has existed for thousands of years. Breeders typically select for desirable heritable traits and discard plants having undesirable traits. Once a breeder is taught what heritable traits are selectable, other breeders are able to replicate the work. The present claims 8-15, 51, 52, and 56-58 address breeder selectable traits that are confirmed in Enola as heritable traits. In this art, that is a sufficient written description for those skilled in the art to recognize exactly what they have in context of the claims and to replicate the results.

The written description requirement is distinct from the enablement requirement. The written description requirement is one of definiteness assuring that one skilled in the art can identify the species that the claims encompass. For example, if one possesses beans in the claimed color range of claim 13, there is definiteness such that one skilled in the art is certain to know whether the claims attach. These claimed characteristics are sufficient to provide an adequate written description of the genus because the recitation, as claimed and disclosed in the Specification, does distinguish the claimed genus from others,. Unlike *University of California*, functional recitation is not an issue.

The enablement requirement exists to assure that others can replicate the results and it is in this context that the number of species usually becomes relevant. Pages 15-16 of the Office Action allege that the Patent Owner possessed Enola, but not other *Phaseolus vulgaris* plants or seeds having characteristics, for example, as recited in claims 8-15. That the Examiner is concerned with the lack of multiple disclosed species indicates confusion between two distinct requirements, namely, that of the *written description* versus

enablement. It is not the case that the claims are broader than enablement in the specification.

Enablement of multiple species does exist because the application teaches breeder-grower selection criteria that can be consistently used to replicate the claimed phenotypic traits. Applicant's ATCC deposit meets the enablement requirement and assures that plant breeders have access to germplasm permitting them to continue the selection process favoring the claimed phenotypic traits for selective propagation in a wide variety of species.

Even without the ATCC deposit, others skilled in the art have followed the Patent Owner's example and are now able to report breeder selection processes that select for color traits to produce field beans in the claimed color range. For example, an attached article, Bassett, *Classical and Molecular Genetic Studies of the Strong Greenish Yellow Seedcoat Color in 'Wagenaar' and 'Enola' Common Bean*, ASHS Journals Online (2000) reports crossing of the Wagenaar variety with seedcoat genotype $C J g b v^{jae}$ to isolate a segregating population of plants exhibiting the SGY (strong greenish yellow) seedcoat characteristic. The article reports that Wagenaar seed is normally canary yellow on the ventral side and schamois on the dorsal side; however, Wagenaar may sometimes exhibit the SGY trait partially as a mottling of SGY and PGY (canary yellow) characteristics. The Bassett article reports that the same SGY recessive gene of Wagenaar may be found in the Patent Owner's own Enola and that the SGY characteristic is distinct from the canary yellow PGY trait reported in previous articles by different authors, such as Prakken. The SGY trait was confirmed by crossing and by comparative crossing with Enola to produce uniform SGY color. These results led Bassett to propose a symbol *gy* for the 'newly discovered' SGY heritable trait, which was accepted and approved by the Genetics Committee of the Bean Improvement Cooperative (GCBIC).

We fail to understand the significance of the assertion on pages 15-16 of the Office Action that Applicant was not in possession of the claimed color characteristics as to other

species than the Enola cultivar on deposit. Since the claims are sufficiently definite to permit others to identify the claimed invention, reference to the number of species would appear only relevant to the possibility of the claims being broader than the enabling disclosure. The issue here is not one of definiteness of the claims, but whether the disclosure is broad enough to support a genus claim, e.g., a genus comprising the color ranges of claims 13 or 51. All that is required for this purpose is that the specification teach those how to make the claimed invention without undue experimentation. *In re Borkowski*, 422 F.2d 904, 908 (CCPA 1970) ("The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation).

Possession of the claimed invention is indicated by the Patent Owner having taught others, like Bassett, how to practice the claimed invention in a manner that enables those skilled in the art to practice the claimed invention. This teaching was done, in context of claims 13 and 51, by teaching how to select for the claimed color as a newly discovered heritable trait. As shown by the Basset article, subsequent research by Basset confirms that others skilled in the art are able to replicate results originally taught by the Patent Owner. Furthermore, the SGY trait was previously not recognized in the art as indicated by GCBIC approval of the gy designation.

In light of the facts that Bassett was able to replicate the Patent Owner's results, and Bassett confirmed this selection by comparative crossing with Enola, it would be incorrect for the Examiner to insist upon the Patent Owner having to show multiple species. In *Ex parte Obukowicz*, 27 USPQ2d 1063, the Appellants' invention concerned a method of combating plant insect pests utilizing plant colonizing bacteria that were genetically modified to produce the protein toxin of *Bacillus thuringiensis*. The modification was accomplished by inserting DNA encoding for the protein toxin into the chromosome of the bacteria. The Examiner, citing an article he himself had written, speculated by presuming

that there would be difficulty in suitably transforming the hosts. The Examiner's presumption was rebutted by Appellant's showing, by way of articles and declarations, that a number of hosts had been suitably transformed by those following the Appellant's methodology. This showing was sufficient to rebut the Examiner's presumption. There is no hard and fast rule about how many species must be disclosed to support a genus claim:

The issue of whether or not undue experimentation is required must be decided on the facts of each case. Reported cases are of limited precedential value. See, e.g., *In re Angstadt*, 537 F.2d 498, 190 USPQ 214 (CCPA 1976); *In re Metcalfe*, 410 F.2d 1378, 161 USPQ 789 (CCPA 1969). It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. *In re Vaeck*, *supra*; *In re Angstadt*, *supra* 537 F.2d at 502-03, 190 USPQ at 218. *Id.* at 1067.

The success of Bassett in reproducing the Patent Owner's success is indicative of reasonableness in the amount of experimentation necessary for him to do so. Bassett merely consulted the bean literature, investigated color characteristics of interest, and embarked upon the same general type of selective breeding campaign taught by the Patent Owner. It is routine in the art that he could do so—once the Patent Owner documented the claimed heritable traits of interest. *In re Wands*, wherein the issue was the predictability of being able to make a particular monoclonal antibody, the court stated:

[e]nablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not experimentation." The court further stated that "[t]he determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *Id.* at 1404. In the plant breeder-selection art at the time this application was filed, those persons of skill routinely expected to perform a significant amount of experimentation to obtain the plants of interest. Thus, applying

the standard of reasonableness as required by *In re Wands*, there is no basis to assert that the experimentation that might be required to produce the claimed plants and plant materials is undue.

The Patent Owner's attorney respectfully traverses the §112 first paragraph rejection, for the reasons explained above, and requests withdrawal of the rejection.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

The Examiner has rejected claims 7, 9, 10, 54, 56 and 57 under 35 U.S.C. § 112, second paragraph. Office Action Sec. 26 ¶ 1. However, in the following paragraphs, the Examiner limits discussion to claims 7, 9, 54, 55, 56 and 57. For lack of further direction, The Patent Owner has responded to the rejection of those claims only.

The Examiner has directed (or suggested) that certain changes be made to claims 7, 9, 54, 55, 56 and 57. The Patent Owner has responded fully to those directions with respect to 7, 9, 10 and 56, and has modified claim 57 in a manner consistent with the Examiner's direction. Claims 54 and 55 are cancelled without prejudice.

Claim Rejections - 35 U.S.C. §§ 102/103

The Examiner's rejections based on 35 U.S.C. § 102/103 are fundamentally flawed. The Examiner bears the burden of making out a *prima facie* case of invalidity. The Examiner has not done so. Rather, the Examiner has erroneously rejected the Patent Owner's claims because the Patent Owner allegedly cannot make out a *prima facie* case of validity.

In support of the Examiner's ruling of invalidity, the Examiner relies upon nine beans identified by specific accession numbers and sections of three textbooks on beans. The Patent Owner has no objection to locating (or attempting to locate) the beans specifically identified by the Examiner. However, the Patent Owner strenuously objects to dealing with the Examiner's citation of bean textbooks.

The textbooks identify dozens of beans. Acquisition of the beans, if they could be acquired, followed by their testing, would be a major research project. This places an unfair and unprecedented burden on the Patent Owner. It transfers the Examiner's burden to the Patent Owner, and in a context where the Patent Owner and the Examiner are on an even footing. The Examiner can access accession databases as well as can the Patent

Owner. If citation of a particular bean is intended, the Patent Owner requests clarification as to what bean is intended.

With respect to the beans specifically identified by the Examiner, six are not publicly available and three are not remotely similar to the bean of the invention. The Patent Owner has made every effort to obtain from CIAT the CIAT beans identified by the Examiner (the same beans identified by CIAT in its request for reexamination). The Patent Owner has contacted both CIAT and its attorney in the reexamination request. Nothing has been received, and the Patent Owner cannot respond to the CIAT citations by the Examiner. The refusal or inability of CIAT to comply with these requests is particularly vexing since it was CIAT that requested the reexamination proceeding. Thus, the Patent Owner is faced with the impossibility of responding to inspecific allegations that amount to arm-waiving by CIAT in the form of a reexamination request that was not properly supported by a color analysis, where the Examiner would now require the Patent Owner to study beans in the possession of CIAT, and where CIAT either does not have or will not release the beans duly requested by the Patent Owner. The premise of shifting the Examiner's burden onto Applicant because Applicant is better equipped to handle these types of studies does not work very well when it is impossible for the Patent Owner to do so. If the Patent Owner bore the burden of making out a prima facie case of validity, as it does not, it has plainly carried its burden with respect to the CIAT beans.

The other three beans cited by the Examiner are GRIN accessions. The Patent Owner has been able to obtain samples of these from the USDA facility in Pullman, Washington. They differ greatly from the bean of the invention. See the attached Declaration of Polly Proctor, paragraphs 8-11

What the Examiner has done in citing a variety of beans as §103 art is to replicate the allegations raised in CIAT's request for reexamination. As described in the preceding paragraph, CIAT has made it impossible for the Patent Owner to respond fully to the rejection by studying the cited beans. What we can say about the missing beans is that the test results scored by Polly Proctor for the obtainable GRIN beans raise significant credibility issues regarding the CIAT allegations which, we again note,

are unsupported by actual color analyses from CIAT. For example, beans that score red are not yellow. With this in mind, we suggest that there is no continuing basis for the Examiner's burden-shifting assumption that the GRIN beans have all the characteristics of the relevant claims of the invention. In fact, it appears that the CIAT allegations are inequitable.

Also relevant are apparent efforts by Agri Sciences, Inc., a large agricultural concern, to develop its own yellow bean. Their public pronouncements supported the conclusion that their development was not based on Enola but on what they referred to as a "Mayacoba" bean. See the Declaration of Polly Proctor Exhibit E. Agri Sciences called their bean "Myasi". When this bean was tested by an expert, it was found that it was not clearly distinguishable from the Enola bean. See the Declaration of Polly Proctor Exhibit D.

The Examiner has not made out a *prima facie* case that the relevant claims of the invention are invalid under 35 U.S.C. § 102. For much the same reasons, the Examiner has not, by a one-sentence assertion of obviousness, made out a *prima facie* case that the relevant claims of the invention are invalid under 35 U.S.C. § 103. If the Examiner's one-sentence assertion is correct, no botanical invention would be patentable in all likelihood.

Information Assessment / Requirement for Information

The Examiner's Information Assessment is premised to some extent on the presumption "that the Enola variety developed after the three rounds of selection did not differ in seed coat color from the originally purchased variety comprised a seed coat color from about 7.5 Y 8.5/4 to about 7.5 Y 8.5/6 in the *Munsell Book of Color* when viewed in natural light." This presumption is incorrect.

In response to this requirement, we have provided the Declaration of Larry Proctor, which describes the conditions under which the source germplasm beans were acquired and developed into Enola. The beans purchased in Mexico were not in a commercial quantity. They were part of a five-pound bag of beans that were purchased in a grocery store in Mexico at the conclusion of a trip to Mexico by the applicant in July 1991. Prior to that trip, the applicant had never seen yellow beans, either in Mexico or the United States.

When he returned to the United States from Mexico, the applicant sorted out from

the bag of beans those that had approximately yellow colored seed coats. The resultant collection varied from light to dark tan. Stated in terms of the *Munsell Book of Color*, these beans fell on various squares of the 2.5 Y page of the *Munsell Book*. In addition, these beans differed significantly from one another in hilar ring color, size, weight and shape. They appeared to applicant to be a collection of varieties rather than a single variety.

Applicant planted the collection of yellow beans in 1991, and pursued a program of selective breeding for three generations. The invention was complete in 1993. For purposes of improving stability, applicant continued to selectively breed the invention through perhaps 1997. The patent states that the Mexican beans were acquired in 1994 and the breeding program started then. This is incorrect. It is an error. The same error was made in applicant's application for a Plant Variety Protection Act Certificate (of record in this proceeding).

The Examiner has inquired whether the beans purchased by the applicant were in public use or on sale in the United States, noting that the field beans may have been "sold at the retail level, sold under a different name, or even distributed to interested parties free of charge." The Patent Owner is not aware of any such event. Applicant developed his invention in secrecy and filed his application less than one year prior to his first public disclosure of his invention.

The Examiner should be aware that the date of sale or public use was an issue in recently-settled litigation in Colorado relating to the Patent Owner's Plant Variety Protection Act Certificate. The arguments and evidence on this issue were complex and convoluted. The Patent Owner will not attempt to address those arguments and evidence here. The relevant documents in the litigation have been made of record in Information Disclosure Statements. The Patent Owner will answer any further questions the Examiner has on this subject.

Conclusion

The Patent Owner has fully addressed the Examiners concerns relating to the specifications and claims. The Patent Owner believes that no fees are due. However, if fees are in fact deemed necessary in connection with this amendment, the Examiner is authorized to charge deposit account number 12-6000. Please call the undersigned with any questions.

Respectfully submitted



Dan Cleveland, Reg. No. 36,106

Lathrop & Gage, L.C.
4845 Pearl East Circle, Suite 300
Boulder, CO 80301
(720) 931-3012
(720) 931-3001 (fax)